GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD, BEVERAGES, AND CONSUMER PRODUCTS

1010 WISCONSIN AVE NW
NINTH FLOOR
WASHINGTON, DC 20007
PHONE (202) 337-9400
FAX (202) 337-4508
www.gmabrands.com

August 30, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0277

Enclosed please find the Grocery Manufacturers of America's preliminary comments and suggestions to the Food and Drug Administration concerning implementation of Section 306 (recordkeeping) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

Sincerely yours,

James H. Skiles
Vice President, General Counsel

02N-0277

EC 7

Before the
U.S. Food and Drug Administration

Implementation of
Public Health Security and Bioterrorism Preparedness and Response Act
of 2002
(PL 107-188)

Docket No. 02N-0277
(Recordkeeping)

COMMENTS OF THE GROCERY MANUFACTURERS OF AMERICA, INC.

August 30, 2002

Introduction

The Grocery Manufacturers of America, Inc. ("GMA") appreciates the opportunity to provide preliminary comments and suggestions to the Food and Drug Administration concerning implementation of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") (PL 107-188). GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

FDA is to be commended for the orderly, open, and efficient manner in which it has approached the implementation of the Bioterrorism Act. As FDA well knows, the time period provided by the Congress for the adoption of regulations required to implement various provisions of the Act is only 18 months. The regulations that FDA is required to adopt –on establishment registration, recordkeeping, and prior notice of food imports – have the potential to disrupt seriously the flow of food in commerce. It is, therefore, critically important that FDA's process for the development of proposed regulations, consideration of comments, and adoption of final regulations continue to provide for maximum public input and that FDA remain fully committed to the issuance of final regulations within the time period provided in the Bioterrorism Act. GMA intends to cooperate fully with FDA to achieve timely and appropriate implementation of the Act.

These comments address section 414 of the Bioterrorism Act which authorizes FDA by regulation to require the maintenance and retention of certain "chain of distribution" records and which authorizes FDA to obtain access to those and other records maintained by food companies. GMA has also filed comments on section 305 (establishment registration), 307 (prior notice of food imports), and 303 (administrative detention).

Maintenance and Retention of Records

Scope

The Bioterrorism Act provides FDA with limited authority to require the maintenance and retention of certain "chain of distribution" records. Under section 414(b) of the Bioterrorism Act, FDA may require the "establishment and maintenance" by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food"

(excluding farms and restaurants) records that will enable FDA to "identify the immediate previous sources and immediate subsequent recipients of food" (referred to as "one up and one back"). The legislative history of this provision makes clear that FDA's authority to require "chain of distribution" records does not extend to records regarding transactions or activities to which a person was not a party. Thus, for example, a food processor can be required to maintain records that show the persons from whom the processor directly received ingredients used to make its products and the persons to whom those products were directly distributed (the distributor, for example, but not the retail stores which received the product from the distributor).

Simple Requirement

The regulations to implement this provision of the Bioterrorism Act need not be complex. There is no need, for example, to specify a form for the maintenance of the chain of distribution information. Rather, the regulations need merely provide that persons subject to the record keeping requirement maintain the "one up and one back" information in a records maintenance system of the person's choosing, including existing systems, so long as the information is reasonably accessible to FDA upon a request that complies with the standard in the Act for access to records. Although most food companies currently maintain the very chain of distribution information that can now be required by regulation, the diversity and complexity of the food industry means that the information is maintained in many different ways and formats, ranging from computerized records systems to file folders of paper records. It should be of no concern to FDA and, therefore, not the subject of the regulations to prescribe any specific manner or form of maintaining the information. Compliance with a chain of distribution records regulation should require only that the person subject to the requirement be able to produce, within a reasonable period of time, "one up and one back" information. The information that FDA should require to be maintained should include only the name and address of the person from whom an article of food was received or to whom it was shipped and a description of the article of food.

Immediate Previous Source Recipient

The Bioterrorism Act does not make clear what is meant by the term, "immediate previous sources" or "immediate subsequent recipients". In theory, at least, the immediate previous source or recipient would be the common carrier or other person who transported the article of food. We do not believe, however, that the Congress intended for that result and suggest, instead, that the immediate previous source or recipient be the company, and not the carrier, from whom the item was received or to whom the item was delivered. Nevertheless, the existing records maintenance systems of many companies will contain the common carrier information.

Specificity

The requirement to maintain "one up and one back" chain of distribution records should not include a requirement that a company be able to associate a specific lot or shipment of an ingredient that it received with a specific lot or shipment of product that it produced or distributed. This information is not reasonably needed and it is often not practical or possible to provide it. Moreover, the language in the Bioterrorism Act is quite clear: it authorizes a regulation to require the maintenance of records that show the person from whom a food processor or distributor received a product and ingredient and the person to whom the processor or distributor sent an ingredient or product. There is nothing in the language of the Act or in its legislative history that would support an interpretation of the recordkeeping requirement that includes a requirement that ingredients or products received be directly associated with ingredients or products that are shipped.

An example will illustrate the point: if a company that produces baked goods obtains flour from multiple sources (as would typically be the case), it would not ordinarily maintain its supply of flour in a way that is segregated by the supplier. Thus, while it would know the identity of all of the persons from whom it received flour, it would not be able to associate a particular supplier's flour with a particular lot of finished baked goods that it produced. Similarly, a distributor who receives 100 cases of a finished product would know to whom those cases were later distributed, but would not and need not maintain a record that relates a particular case to a particular recipient. The fact that this level of specificity is not contained under current chain of distribution records maintenance and the practical difficulties of maintaining it, as well as the absence of any concrete evidence that it is essential for FDA to have, all argue strongly for a more general "one up and one back" requirement. In the first example, the baked goods processor should be required to maintain records to identify the persons from whom the flour was received and to the persons to whom the baked goods were distributed, but no more. In the second example, the distributor should be required to maintain records of the persons from whom product was received (and, of course, the identity of that product) and the persons to whom the product was sent, but no more. If, pursuant to the Act, FDA obtains access to that information, it is sufficient to permit FDA to follow the trail of a potentially adulterated ingredient or finished product. Obviously, if a company does maintain its chain of distribution records with more specificity, those records can be provided to FDA on request.

Exemption

There is a need for a practical exemption from the requirement to maintain records of the "immediate subsequent recipients" of food. Many companies maintain "company stores" at their facilities where visitors and others may purchase items produced by the company at the facility. It would be impractical to require the company to maintain a

record of each individual consumer who purchases product at such a "company store" and such information is not reasonably needed by FDA.

Retention

The Bioterrorism Act provides that regulations to require the maintenance and retention of chain of distribution records may not require that such records be maintained for longer than two years (section 414(b)). We suggest that FDA adopt a simple, two-part approach to the retention period. Such an approach will avoid unneeded complexity and decision-making by persons required to maintain these records. We suggest that the regulations provide that "one up and one back" chain of distribution records be maintained for two years from the date of receipt or distribution, as the case may be, except that records related to perishable foods need only be maintained for six months from the date of receipt or distribution. This approach will not be difficult for companies to understand or comply with, while ensuring that chain of distribution records are maintained for the period of time in which they may be needed to trace instances of adulterated product that presents a serious threat of adverse health consequences or death.

We also suggest that the date which triggers the retention period (that is, two years from what event?), should be the date on which an article of food is either received at a facility in the United States or shipped from such a facility, even though, for example, a company may have taken title to the article on a different date or taken custody at a location outside the United States. The date of receipt or distribution within the United States is an easily discernable event for which a record is likely to exist. Compliance with the retention requirement will thus be facilitated for companies. At the same time, FDA will have no difficulty in determining whether a record has been retained for the appropriate period of time.

Records Access

We understand that it is not FDA's current intention to address issues of access to records under section 414 of the Bioterrorism Act in the current rulemaking. Nevertheless, there are several issues related to records access that are of singular importance to the food industry that warrant FDA's careful attention as it proceeds to implement the Act. We address those issues here briefly.

First, the standard for access to records was one of the most hotly contested issues during the legislative consideration of the Bioterrorism Act. The standard that was ultimately accepted by the Congress – "reasonable belief that an article of food is adulterated and presents a serious threat of adverse health consequences or death to humans or animals"—represents a compromise between the need to provide FDA access to records to investigate the most serious threats to the safety of the food supply

and the equally compelling need to ensure that FDA inspectors are not at liberty to rummage through highly confidential and competitively valuable corporate records during each factory inspection.

The standard in section 414 has several elements, each of which need to be satisfied in order for a request for access to records to be lawful. First, FDA must possess a "reasonable belief." In order for FDA's belief to be reasonable, it must be predicated on concrete evidence and not on mere allegation, hearsay, or innuendo. The evidence must support a strong probability (the "belief") that the food is adulterated and presents a serious threat. Further, the evidence that supports the "reasonable belief" must be capable of being assessed by a third party, such as a court. Ordinarily, therefore, in order for FDA to have a "reasonable belief," it must possess some objective evidence, such as analytical data, which may be supplemented by other data and information.

It is also important that FDA pay careful attention to the last two elements of the standard for records access—the reasonable belief that an article of food is adulterated and presents a serious risk of adverse health consequences or death to humans or animals. Congress included the requirement that there be a reasonable belief that the food is adulterated because that is the traditional basis on which the agency and the industry conceive of food that may present a risk to health. The last part of the standard for records access is patterned, of course, on the standard for a Class I recall and is clearly intended to reserve records access for those cases in which there is a strong probability of a serious problem with an article of food such that consumers will be exposed to serious threats to their health if the food is consumed. There is nothing in the standard for records access that would support its invocation on a routine basis.

Second, because of the high standard that the Act imposes on FDA before records access may be obtained, it is important that FDA adopt internal procedures to ensure that the assertion of records access by agency employees occurs only after careful consideration of the matter by senior FDA officials. We suggest that FDA adopt internal guidance that provides that the records access authority may only be invoked if approved by the District Director for the FDA district in which the records are located and the senior compliance official in the Center for Food Safety and Applied Nutrition. This procedure will help to provide assurance to the food industry that requests for access to records have been given appropriate consideration by senior FDA officials and will thus minimize the likelihood of disagreements with inspectors who arrive at facilities with a records request in hand.

Finally, it is imperative that FDA adopts appropriate procedures to protect the confidentiality of information that it may obtain through the new records access provision of the Act. Indeed, section 414(c) of the Act requires that the agency "take appropriate measures to ensure" that there are procedures in place to protect against the disclosure of confidential and trade secret information. The importance that the

Congress attached to the protection of this information is demonstrated by the fact that the Act amends section 301(j) to include the disclosure of information obtained under section 414 as a "prohibited act." Although the records access provided by section 414 is now effective, FDA should not resort to it until it has in place the "appropriate measures" that are called for under the Act. Those measures must ensure that the records obtained by FDA under its authority are protected from disclosure if FDA shares them with other regulatory bodies.

Conclusions

The regulations to require the maintenance of the limited chain of distribution records under section 414 of the Act should be performance based. There is no need to specify the form or manner in which the information is to be kept by a person subject to the recordkeeping requirement. Information beyond the name and address of the "immediate previous sources and the immediate subsequent recipients" of food and a description of the article of food received or shipped is sufficient.

The records access provision should be used judicially with appropriate review within FDA before records are sought. Procedures should be put in place to ensure that records obtained by FDA are held in confidence.